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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,077	02/19/2004	Sylvic Demay	069208.0118	4531

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BAKER BOTTS, LLP
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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT	PAPER NUMBER
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3736

MAIL DATE	DELIVERY MODE
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06/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/782,077	Applicant(s) DEMAY ET AL.	
	Examiner Jeffrey G. Hoekstra	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 14, 16 and 20-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 14, 16 and 20-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on 04/09/2007, amended claim(s) 1, 6-9, 16, and 20-26 is/are acknowledged. The current rejections of the claim(s) 1-9, 14, 16, and 20-28 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-9, 14, 20-22, and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathias et al (US 6,387,086) in view of Eichhorn et al (US 4,320,769).

4. For claims 1, 2, and 20, Mathias et al discloses a bag system for collecting a biological fluid (e.g. blood) (see Abstract) initially void of biological fluid, comprising:

- a collection device (10);
- a fluid collection bag (16) in fluid communication with the collection device;
- a sampling device (18) in fluid communication with the collection device, the sampling device including:
 - at least one sampling receptacle (70); and
 - a transfer device (68 as best seen in Figure 4D) having an associating device (the inside faces of element 68);

Art Unit: 3736

- wherein the associating device includes a guide (98 and 100) having a set of longitudinally disposed deformable projections (the inside face of elements 98 and 100).

5. For claim 3, Mathias et al discloses a system, further comprising: a first tube (15) between the collection device and the fluid collection bag and a second tube (62) between the collection device and the sampling device.

6. For claim 4, Mathias et al discloses a system, wherein the sampling device (18) further comprises a sampling bag (42) connected to the downstream end of the second tube.

7. For claims 5 and 21, Mathias et al discloses a system, wherein the receptacle (70) has a body having a first diameter and further comprises a closure element (84) having a second diameter greater than the first diameter.

8. For claims 6 and 21, Mathias et al discloses a system, wherein the transfer device further comprises: said guide (68) open at a front part and a hollow needle (74 & Column 6, lines 52-55) in fluid communication with the bag system.

9. For claim 14, Mathias et al discloses a system, wherein the guide further comprises a cap having a tamper-evident element (17).

10. Mathias et al discloses the claimed invention except for explicitly disclosing the guide having two sets of deformable projections distributed longitudinally on an internal face of the guide wherein a first set of the projections disposed near the needle is breakable under deformation. Eichhorn et al teaches a guide (10 and 100) having two sets of deformable projections (12 and 102) distributed longitudinally on an internal face

Art Unit: 3736

of the guide wherein a first set of the projections disposed near the needle is capable of breaking under deformation and wherein a second set of projections is located near a front region of the guide (as best seen in Figures 2 and 10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the fluid collection system as taught by Mathias et al, with the projections as taught by Eichhorn et al for the purpose of increasing the efficacy of a bodily fluid withdrawal system to function safely with respect to the patient and caretaker.

11. Claims 16 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathias et al in view of Eichhorn et al as applied to claims 1-9, 14, 20-22, and 27-28 above, and further in view of Ishida (US 5,125,920).

12. Mathias et al in view of Eichhorn et al discloses the claimed invention, as aforementioned, except for explicitly disclosing a collection bag and receptacle with at least two identification tags. Ishida teaches a identification tags disposed on the collection bag (25) and disposed on the receptacle (26 and 27 & Column 5, lines 16-23), wherein the tags allows the establishment, after their dissociation, that both the collection bag and receptacle originated from the same bag system (Column 5, lines 37-39). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the fluid collection system as taught by Mathias et al in view of Eichhorn et al, with identification as taught by Ishida for the purpose of increasing the efficacy of a bodily fluid withdrawal system to function safely with respect to the patient and caretaker.

Response to Arguments

13. Applicant's arguments filed 04/09/2007 have been fully considered but they are not persuasive. Applicant argues the rejection of claims 1-9, 14, 16, and 20-28 under 103(a) as being unpatentable over Mathias et al in view of Eichhorn et al and over Mathias et al in view of Eichhorn et al and further in view of Ishida, specifically arguing (a) there is no motivation to combine the references to meet the claimed limitations, (b) the references do not disclose, teach, or fairly suggest a first and second set of projections, and (c) the references do not disclose, teach, or fairly suggest a first and second set of projections wherein the first set of projections is operable to support the receptacle in a transfer position and the second set of projections is operable to support the receptacle in a standby position. The Examiner disagrees, maintains the rejections, and notes the following:

14. In response to applicant's argument (a) that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Mathias, Eichhorn, and Ishida are concerned with configuring a system for the withdrawal and collection of biological fluid.

Art Unit: 3736

15. In response to applicant's argument (b) that the references do not disclose, teach, or fairly suggest a first and second set of projections, the Examiner maintains Eichhorn et al teaches a first and second set of projections as broadly as claimed. The Examiner notes Eichhorn et al teaches a plurality of deformable projections (12 and 102) distributed longitudinally and comprising first (2 of the 4 ribs positively recited at least in column 3 lines 5-10) and second (the other 2 of the 4 ribs positively recited at least in column 3 lines 5-10) sets wherein the first set of the projections disposed near the needle (section 106 of 2 of the 4 ribs) is capable of breaking under deformation and wherein a second set of projections (section 104 of the other 2 of the 4 ribs) is located near a front region (the right most region of Figure 10) of the guide (as best seen in Figures 2 and 10) (column 1 lines 51-62, column 2 line 50 – column 3 line 58, and column 4 lines 60-64).

16. In response to applicant's argument that (c), a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Conclusion

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

Art Unit: 3736

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571) 272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.H./

Jeff Hoekstra

Examiner, Art Unit 3736


MAX F. WINDENBURG
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